

REMARKS

Claim 18 has been canceled without prejudice. Claim 26 has been amended to refer to specific regions of SEQ ID NO:3. Support for this amendment is found in the original specification. No new matter has been added.

The following remarks are in response to the Office Action mailed October 22, 2007 ("the Office Action").

Rejections under 35 U.S.C. § 101/ 112, first paragraph (enablement)

Claims 1, 8, 15-18, 23, and 26 were rejected as lacking patentable utility.

To properly reject a claimed invention under 35 U.S.C. 101, the Office must (A) make a prima facie showing that the claimed invention lacks utility, and (B) provide a sufficient evidentiary basis for factual assumptions relied upon in establishing the prima facie showing. *In re Gaubert*, 524 F.2d 1222, 1224, 187 USPQ 664, 666 (CCPA 1975). A prima facie showing has not been made. Applicant submits that the claimed polypeptides have asserted and well established utilities.

First, the Office Action alleged that the claims lack specific utility. The Office Action stated, "The polypeptide encoded by a nucleic acid comprising the nucleotides 585-2156, 2307-5741, and 5620-7533 of SEQ ID NO:3 lacks a specific utility...Indeed, no polypeptides or polypeptides [sic] sequences are taught in the specification" (page 2, carryover paragraph to page 3).

Applicant disagrees with the statement in the Office Action at page 3 that "no polypeptides or polypeptides sequences are taught in the specification." As noted previously (but not acknowledged in the Office Action), **the specification discloses polypeptides and polypeptide sequences**. See, e.g., Figures 2 and 3 of the original specification. See also page 42, line 34, to page 43, line 16. In view of the disclosure of the specification, Applicant requests that this be acknowledged, or that the Examiner clarify what is meant by the assertion that "no polypeptides or polypeptide sequences" are disclosed.

The Office Action alleged that the claimed sequences lack utility because

Aliyoshi [sic, Akiyoshi] et al...teach a retrovirus having 99.9% identity to SEQ ID NO:3 (5 mismatches), and encoding the env protein (Fig. 1)...Akiyoshi et al. teach that Type C retroviruses from swine cell lines are known but no disease following infection has been identified. Therefore, it can be concluded that the polypeptide(s) encoded by specified regions of SEQ ID NO:3...do not have a specific utility (Office Action, pages 3-4).

This part of the rejection is not understood. Lack of utility is not established by Akiyoshi et al. (J. Virol. 72(5):4503-4507, 1998). Utility does not turn on whether or not a single reference reports a disease associated with a swine retrovirus. If anything, Akiyoshi et al. **supports** utility of swine retroviral polypeptides. The reference reports that "[e]ndogenous retroviruses are a concern in the use of pig-derived tissues for xenotransplantation into humans" (abstract, first sentence). Thus, Akiyoshi et al. consider swine retroviruses to have clinical relevance. In addition, Akiyoshi et al. discusses conserved residues and functional motifs in swine retroviral gag, pol, and env polypeptides, indicating biological activities associated with the polypeptides (see Akiyoshi at page 4504, right column, to page 4505, left column). Akiyoshi et al., and the other references cited by the Examiner which discuss various retroviral polypeptides, would not cause one to question the utilities of Applicant's polypeptides.

The Office Action also stated that "[t]he polypeptides have not been taught to have a substantial utility, or real world use. While SEQ ID NO:3...may be a retrovirus, the specification does not teach the function of the encoded proteins" (page 4). Applicant disagrees that SEQ ID NO:3 "may be" a retrovirus. The sequence indeed corresponds to that of a retrovirus, as asserted in the specification. The Examiner has not offered any evidence to the contrary.

The Office Action maintained that the specification "does not assert any utility" (page 4). Applicant disagrees. The specification teaches methods and reagents for detecting porcine retroviruses that are useful, e.g., for screening donor animals and xenografts recipients to determine infection and as a measure of the appropriate level of immune suppression (specification, page 30, lines 25-27). The methods can include contacting a tissue sample with an antibody specific for a retroviral protein. See the specification, e.g., at page 24, lines 23-28. The specification also teaches ELISA-based assays for detecting the presence of porcine retroviral polypeptides. The ELISA assays include generation of porcine retroviral polypeptides

and generation of antibodies specific for the polypeptides. See the specification, e.g., at page 39, lines 13-20. The Examiner's assertion that the specification "does not assert any utility" is incorrect.

If an applicant has asserted that a claimed invention is useful for any particular practical purpose (i.e., it has a "specific and substantial utility") and the assertion would be considered credible by a person of ordinary skill in the art, a rejection based on lack of utility should not be imposed. MPEP 2107.II.B.1. For product claims, disclosure of **one** specific, substantial, and credible utility meets the criteria of 35 U.S.C. § 101.

Asserted utilities have been noted. The specification discloses methods of using the claimed polypeptides, e.g., for detecting porcine retroviruses and determining infection in animals. In contending that disclosed methods of using the claimed polypeptides lack utility, the Examiner stated, "Since this method is carried out using the polypeptides claimed, it is a non-specific utility" (Office Action, page 4). The logic of this statement is unclear. Methods of using the claimed polypeptides *are* utilities. These utilities are specific. A specific utility is specific to the subject matter claimed. Not all proteins are useful in methods for detecting porcine retroviruses, e.g., in methods of evaluating risk of porcine retroviral transmission. These are not general utilities that would be applicable to the broad class of the invention. The Examiner's basis for finding the utilities non-specific is not understood.

The Office Action maintained that asserted utilities are "reach through" utilities because one must make all of the polypeptides encoded by SEQ ID NO:3...then determine for themselves if the detection of these polypeptides has any bearing on xenograft transfer...One cannot know until they determine for themselves if detection of any one of the polypeptides will be an indication that a donor animal will pass the nucleic acid retroviral vector to the xenograft recipient and cause deleterious effects. Thus, the polypeptides encoded by specific regions of SEQ ID NO:3 lack a specific utility (page 5).

The above-quoted remarks from the Office Action do not actually go to the specificity of the asserted utilities. Rather, they seem to allege that the utilities are not credible or substantial. Applicant again notes the standard for credibility in evaluating utility. An assertion of utility is credible unless (A) the logic underlying the assertion is seriously flawed, or (B) the facts upon which the assertion is based are inconsistent with the logic underlying the assertion. MPEP

2107.2.III.B. The logic underlying the assertion that the claimed polypeptides are useful, e.g., in detection of retroviral activation in the context of xenotransplantation is neither “seriously flawed” nor “based on facts inconsistent with that logic.” The concept of using the polypeptides as asserted is not inherently unbelievable, nor does it involve implausible scientific principles. The nature of the claimed polypeptides is not such that one of skill would reasonably doubt their usefulness. Regarding substantiality, Applicant notes that the asserted utilities have real-world applicability and are not merely “throw away” utilities.

The Examiner stated that “using ELISA to detect the claimed polypeptides is tantamount to isolating the polypeptide, which is a circular utility” (Office Action, page 5). This statement, and its relevance to utility, is not understood. One use of the claimed polypeptides is in ELISA assays, and for developing reagents for the assays, to detect retroviral proteins in a test sample. The fact that one’s goal is performing the assays is to detect retroviral proteins (e.g., retroviral proteins expressed as a result of a natural infection) in a test sample does not render these uses of the polypeptides “circular.” Furthermore, one need not know the detailed biological functions of the polypeptides to carry out these methods. The Office Action’s emphasis on lack of functional data in this context is misplaced.

Well Established Utilities

In the amendment filed September 5, 2007, well established utilities for the claimed polypeptides were discussed. Well established utilities are those which are immediately apparent to those of skill in the art, or implied by the specification’s disclosure, and which are also specific, substantial, and credible. As noted in the prior amendment, retroviral polypeptides have well known functions immediately apparent to those of skill in the art. Rather than consider these utilities, the Office Action simply dismissed them because, it alleged, “the function of the polypeptides encoded by SEQ ID NO:3 is not known” (page 6).

This conclusion in the Office Action contradicts the knowledge of those of skill regarding retroviruses. It also contradicts references cited by the Examiner that discuss the functions of retroviral polypeptides, including the swine retroviral polypeptides described in Akiyoshi et al.¹ For example, Akiyoshi et al. identified a region in the gag polypeptide that corresponds to a Cys-

¹ According to the Office Action, Akiyoshi et al. discloses a sequence at least 95% identical to SEQ ID NO:3.

His motif required for efficient RNA packaging in type C retroviruses (Akiyoshi et al., page 4504, right column, first full paragraph). Akiyoshi et al. refers to the highly conserved reverse transcriptase sequence in the pol polypeptide (Akiyoshi et al., page 4504, right column, second full paragraph). Cleavage sites and cell attachment functions of the env polypeptide are noted (Akiyoshi, page 4505, left column, first full paragraph). Many functions of the claimed polypeptides are immediately apparent to those skilled in the art.

Applicant respectfully requests withdrawal of the rejection of claims 1, 8, 15-17, and 26 as lacking patentable utility.

Rejections under 35 U.S.C. § 112, first paragraph (written description)

Claims 1, 8, 15-18, and 26 were rejected as allegedly failing to comply with the written description requirement. The Office Action stated:

The specification and claims do not set forth any structure or function for the claimed polypeptides encoded by specified regions of SEQ ID NO:3, having at least 95% identity to SEQ ID NO:3, or having at least 30 or 100 nucleotides from SEQ ID NO:3. Also, this polypeptide is not in hand (page 6, carryover paragraph to page 7).

Applicant respectfully traverses this rejection. The assertion that the specification and claims do not set forth "any structure" is incorrect. As noted previously (but not acknowledged by the Examiner in the Office Action), the specification discloses SEQ ID NO:3 and polypeptides encoded by SEQ ID NO:3. See Figure 3. Thus, the specification provides **complete** structure of polypeptides that fall within the claims.

The Office Action argues that "there is no correlation of structure with function. Therefore, one skilled in the art could not determine which polypeptides fall within the claimed invention" (page 7). Applicant disagrees. One of skill can determine whether a purified polypeptide is encoded by a nucleic acid molecule at least 95% identical to one of the regions of SEQ ID NO:3 recited in claim 1.

The Examiner argued that "it is not enough to know that Gag proteins aid in the assembly of viral particles in general" (page 7). The purpose of the written description requirement is to clearly convey the information that an applicant has invented the subject matter which is claimed. Another objective is to put the public in possession of what the application claims as

the invention. To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the invention had possession of the claimed invention. MPEP 2163. The specification's disclosure of sequences and identification of the polypeptides as gag, pol, and env gene products provide a combination of distinguishing structural and functional characteristics that meets the standard.

Regarding the Examiner's assertion that the information offered is "not enough," Applicant notes that written description does not require an applicant to spell out every detail of the invention in the specification. Only enough must be included to convince a person of ordinary skill in the art that the inventor possessed the invention and to enable such a person to make and use the invention without undue experimentation. See *Falkner v. Inglis*, 448 F.3d 1357, 1364 (Fed. Cir. 2006)(citing *LizardTech, Inc. v. Earth Resource Mapping, PTY, Inc.*, 424 F.3d 1336, 1345 (Fed. Cir. 2005). Again, the high level of structure recited in the claims, and the disclosure of the specification, would convince one of skill that Applicant possessed the invention.

Applicant respectfully requests withdrawal of the rejection of claims 1, 8, 15-17, and 26, as lacking written description.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 1, 8, 15-18 and 26 were rejected as indefinite.

First, the Office Action stated that "[t]he claims refer to 'A polypeptide...'...retroviruses encode many polypeptides; therefore, it is not clear which polypeptide is being claimed" (page 8).

Applicant traverses this rejection. Claims 1, 8, 15-17, and claim 26, as amended, all refer to polypeptides encoded by specific regions of SEQ ID NO:3. Polypeptide sequences encoded by these regions are depicted in Figure 3. Because the sequences are provided, there is no lack of clarity in these claims. Furthermore, the use of the article "A" in claims 1, 8, and 26 is the proper format for referring to the claimed polypeptides, because these do not have antecedent basis when first introduced in the independent claims.

The Examiner repeated this rejection on the ground that one allegedly cannot know what the term “95% identical” means. The Examiner agreed that the term “percent identity” is the correct term when comparing amino acid sequences but argued that “the term ‘identical’ is not used to describe similarity, because one thing is identical to another or it is not” (Office Action, page 8). This basis for rejection is improper. In the Amendment filed on September 5, 2007, it was explained that the term “identical” has an art-recognized meaning, which is also set forth in the specification at page 25, lines 23-33. The reference in this passage of the specification to “similarity” clearly refers to overall similarity, i.e., the degree of relatedness. The specification states:

“Homologous”, as used herein, refers to the sequence similarity between two polypeptide molecules or between two nucleic acid molecules. When a position in both of the two compared sequences is occupied by the **same** amino acid or base monomer subunit, e.g., if a position in each of two DNA molecules is occupied by adenine, **then the molecules are homologous at that position**” (page 25, lines 23-33; emphasis added).

The discussion of “similarity” in this context does not render the claims indefinite. The degree of similarity clearly relates to the number of positions at which two structures share the same monomeric subunits, which is the same as the degree of identity. Claim 1 uses the term “identity” and the Examiner agreed that the term is clear.

The rejection of claim 18 is moot in view of the cancellation of this claim.

It is noted that none of the stated reasons for rejection under 35 U.S.C. § 112, second paragraph, appear to apply to claims 15-17.

Applicants request withdrawal of the rejection of claims 1, 8, 15-18 and 26, as indefinite.

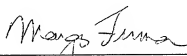
Applicant : Jay A. Fishman
Serial No. : 10/723,552
Filed : November 26, 2003
Page : 12 of 12

Attorney's Docket No.: 14846-011004 / MGH 0978-2D

No fees are believed to be due. Please apply any charges or credits to deposit account 06-1050, referencing attorney docket no. 14846-011004.

Respectfully submitted,

Date: October 31, 2007



Margo H. Furman, Ph.D.
Reg. No. 59,812

Fish & Richardson P.C.
225 Franklin Street
Boston, MA 02110
Telephone: (617) 542-5070
Facsimile: (617) 542-8906